

Amendment and Response

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Applicant: Boldogh et al.

Serial No.: 10/691,330

Filed: October 22, 2003

Title: USE OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF AS
INHIBITORS OF APOPTOSIS AND OTHER CELLULAR DAMAGE**Remarks**

The Office Action mailed June 8, 2006 has been received and reviewed. Claims 1 and 12 having been amended, the pending claims are claims 1-6, 8, and 12-15. Claims 1 and 12 have been amended to correct an inadvertent typographical error (the omission of a comma after the recitation SEQ ID NO:1). Applicants submit that no new matter is added thereby. Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting Rejections

According to MPEP § 804, "[i]n determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" And, while "[a] double patenting rejection of the obviousness-type is 'analogous to . . . the nonobviousness requirement of 35 U.S.C. 103,'" a major distinction is "that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). . . . When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992)." Applicants respectfully submit that the Examiner has improperly relied on the teachings of the instant specification in rejecting the pending claims under the doctrine of obviousness-type double patenting.

Double Patenting Rejection over claims 1-8 of U.S. Patent No. 6,500,798

Claims 1-6, 8, and 12-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,500,798. This rejection is respectfully traversed.

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Pending claims 1-6 and 8 are drawn to a "method for inhibiting apoptosis in a cell, the method comprising contacting the cell with an effective amount of an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin and combinations thereof; wherein the constituent peptide of colostrinin is selected from the group consisting of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), and LKPFPKCLKVEVFPPF (SEQ ID NO: 8); and wherein the apoptosis inhibitor inhibits apoptosis in the cell." Pending claims 12-15 are drawn to a "method for protecting against DNA damage in a cell, the method comprising contacting the cell with an effective amount of a compound selected from the group consisting of colostrinin, a constituent peptide of colostrinin, and combinations thereof; wherein the constituent peptide of colostrinin is selected from the group consisting of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), and LKPFPKCLKVEVFPPF (SEQ ID NO: 8); and wherein the compound protects the cell against DNA damage."

Claims 1-7 of U.S. Patent No. 6,500,798 are drawn to a "method for modulating the oxidative stress level in a cell, the method comprising contacting the cell with an oxidative stress regulator under conditions effective to decrease the level of an oxidizing species present in the cell in response to an oxidative stress compared to the same conditions when the oxidative stress regulator is not present; wherein the oxidative stress regulator is colostrinin, a constituent peptide thereof, an active analog of a constituent peptide of colostrinin selected from the group of SEQ ID NO:1 through SEQ ID NO:34 and combinations thereof" and claim 8 is drawn to a "method for modulating the oxidative stress level in a cell, the method comprising contacting the cell with an oxidative stress regulator under conditions effective to prevent or reduce an increase in the level of an oxidizing species in the cell in response to an oxidative stress compared to the

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same conditions when the oxidative stress regulator is not present; wherein the oxidative stress regulator is colostrinin, a constituent peptide thereof, an active analog of a constituent peptide of colostrinin selected from the group of SEQ ID NO:1 through SEQ ID NO: 34 and combinations thereof."

In rejecting pending claims 1-6, 8, and 12-15, the Examiner asserted "the specification indicates UV-irradiation is a major cause of oxidative stress in the cells and may induce apoptosis (Example 8, pages 28-29) . . . [and b]oth sets of claims are directed to a method for inhibiting apoptosis or a method for modulating the oxidative stress level in a cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combinations thereof in response to apoptosis or an oxidative stress such as UV-irradiation " (pages 3-4, Office Action mailed June 8, 2006). Therefore claims 1-6, 8 and 12-15 in the instant application and claims 1-8 of the patent are obvious variations of a method for inhibiting apoptosis or a method for modulating the oxidative stress in a cell." Applicants disagree.

First, Applicants submit that the Examiner is improperly using the teachings of the specification to substantiate a rejection under the judicially created doctrine of obviousness-type double patenting. Further, Applicants submit that the Examiner has misinterpreted the teachings of the specification. Example 8 of the specification states that "[b]esides being a major cause of oxidative stress in the cells, UVB-irradiation induces apoptosis by a large number of related pathways such as enhanced Fas transcription and/or mRNA stability, induction of transcriptional factors via c-fos, c-jun, SAP-1 and nuclear factor kB gene expression" (page 29, lines 5-9 of the specification). Applicants submit that the specification discloses that the induction of oxidative stress and the induction of apoptosis are mechanistically separate pathways within the cell, and are not obvious one over the other, as asserted by the Examiner.

Reconsideration and withdrawal of the rejection of pending claims 1-6, 8, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,500,798 is respectfully requested.

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Double Patenting Rejection over claims 1-10 of U.S. Patent No. 6,903,068

Claims 1-6, 8, and 12-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,903,068. This rejection is respectfully travcrsed.

Claims 1-6, 8, and 12-15, drawn to methods for inhibiting apoptosis and protecting against DNA damage, are as summarized in the section above. Claims 1-10 of U.S. Patent No. 6,903,068 are drawn to a "method for inducing a cytokine in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is selected from the group consisting of a constituent peptide of colostrinin, an active analog thereof, and combinations thereof" (claims 1-5) and a "method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is selected from the group consisting of a constituent peptide of colostrinin, an active analog thereof, and combinations thereof . . . and wherein said active analog modulates an immune response" (claims 6-10).

In rejecting pending claims 1-6, 8, and 12-15 as "obvious variations" of claims 1-10 of U.S. Patent No. 6,903,068, the Examiner asserted that "the specification indicates that colostrinin induces a variety of cytokines in leukocytes or modulates cytokine production (page 8, lines 11-15; page 22, lines 32-33; page 29, lines 24-20)" (see pages 4-5, Office Action mailed June 8, 2006). Applicants submit that the Examiner is inappropriately relying on the teachings of the currently pending specification to substantiate a rejection under the judicially created doctrine of obviousness-type double patenting. Further, Applicants submit that the present methods of claims 1-6, 8, and 12-15 are patentably distinct from the methods of claims 1-10 of U.S. Patent No. 6,903,068.

Reconsideration and withdrawal of the rejection of pending claims 1-6, 8, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,903,068 is respectfully requested.

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Double Patenting Rejection over claims 1-7 of Co-pending Application 10/691,157

Claims 1-6, 8, and 12-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of co-pending application 10/691,157. This rejection is respectfully traversed.

Claims 1-6, 8, and 12-15, drawn to methods for inhibiting apoptosis and protecting against DNA damage, are as previously summarized. Claims 1-7 of co-pending Application 10/691,157 are drawn to a "method of modulating an intracellular signaling molecule in a cell, the method comprising contacting the cell with an effective amount of a modulator selected from the group consisting of colostrinin, a constituent peptide of colostrinin, and combinations thereof, under conditions effective to accomplish at least one of the following: reduce 4-hydroxynonenal (4HNE)-protein adduct formation; inhibit 4HNE-mediated glutathione depletion; inhibit 4HNE-induced activation of p53 protein; or inhibit 4HNE-induced activation of c-Jun NH2-terminal kinases; wherein the constituent peptide of colostrinin is selected from the group consisting of MQPPPLP (SEQ ID NO:1) LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), and LKPFPLKVEVFPP (SEQ ID NO:8)" (claims 1-6) and a "method of down regulating the 4-hydroxynonenal (4HNE)-mediated oxidative damage associated with lipid peroxidation in a cell, the method comprising contacting the cell with an effective amount of a modulator selected from the group consisting of colostrinin, a constituent peptide of colostrinin, and combinations thereof; wherein the constituent peptide of colostrinin is selected from the group consisting of SEQ ID NO:1 through SEQ ID NO:8; and wherein 4HNE-mediated oxidative damage associated with lipid peroxidation in the cell is down regulated" (claim 7).

In rejecting pending claims 1-6, 8, and 12-15, the Examiner asserted that "the specification indicates 4-HNE (4-hydroxynonenal) induces apoptosis (Example 7, page 28)" and thus, the presently claimed method for inhibiting apoptosis and for protecting against DNA

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damage are "obvious variations" of the methods of claims 1-7 of co-pending Application 10/691,157. Applicants disagree. Applicants respectfully submit that the Examiner is inappropriately relying on the teachings of the currently pending specification to substantiate a rejection under the judicially created doctrine of obviousness-type double patenting. Further, Applicants submit that the present methods of claims 1-6, 8, and 12-15 are patentably distinct from the methods of claims 1-7 of co-pending Application 10/691,157.

Reconsideration and withdrawal of the rejection of pending claims 1-6, 8, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of co-pending Application 10/691,157 is respectfully requested.

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It is respectfully submitted that the pending claims 1-6, 8, and 12-15 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17th day of August, 2006, at 9:25am (Central Time).

By: Sam E. Wigrant
Name: Sam E. Wigrant